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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,301	11/03/2000	Koichi Saito	207198	6724

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/706,301	Saito et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 27, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment and remarks, filed 2/27/03, are acknowledged.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15, and newly added claims 16-17, stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 12, mailed 11/01/02.

Applicant's arguments, filed 2/27/03, have been fully considered but they are not persuasive. Applicant argues that the W/O/W vaccine of the instant claims is different from the W/O/W vaccine known in the art at the time of the invention in that the outer aqueous phase of the instant vaccine consists of a particular polyethylene glycol (PEG) derivative conferring upon the vaccine of the instant claims surprising and unexpected benefits, including reduced viscosity and improved stability.

Applicant is advised that the properties and advantages of the vaccine of the instant claims are not at issue, but rather, the issue is whether or not the specification adequately discloses how to make the vaccines encompassed by the instant claims and whether or not the specification adequately discloses how to use all the encompassed embodiments of said vaccine.

Applicant states that Examples 1-9 describe W/O/W vaccines of the instant claims 1-9, whereas Comparative Examples 1-7 describe W/O/W vaccines, absent the PEG outer aqueous layer, 10-16. Applicant indicates that "The vaccines in Examples 1-9 and Comparative Examples 1-7 are produced in essentially the same manner, with the exception of the addition of a PEG derivative to the outer aqueous layer in the vaccines of Examples 1-9. An overview of the preparation of W/O/W oil type adjuvant vaccines is summarized in Figures A - D (attached hereto)." Applicant

then provides a summary of the method of producing the vaccines of the instant claims referring to Figures A-D.

Applicant is advised that no figures were found attached to the amendment. Regardless, the specification itself must teach how to make and use the claimed invention.

Applicant indicates that,

"Example 1 describes the method of producing vaccine 1. As summarized in Figure A and described on page 14, line 22, through page 15, line 15, of the specification, an antigen suspension was added to a mixture of ethyl oleate, sorbitan sesquioleate, polyoxyethylene(40) hydrogenated castor oil, and an aqueous solution of sodium glutamate and sorbitol (see specification Table 1, W/0-1). The composition was stirred at 12,000 rpm for 5 minutes to create a W/0 type emulsion. A mixture of polyoxyethylene(60) hydrogenated castor oil, polyoxyethylene(196) polyoxypropylen(67) glycol, Macrogol 6000 (a PEG derivative), and phosphate buffered saline (see specification Table 3, outer aqueous phase 1) was combined with the W/0 type emulsion and stirred at 9,000 rpm for 5 minutes to create the W/O/W oil adjuvant vaccine 1 of the present invention."

Page 14, line 22, through page 15, line 15 of the specification discloses,

"[preparation of oil adjuvant vaccine]"

"The oil adjuvant vaccine used in each of the following Examples was prepared by the following method using CLEARMIX CLM-0.8S (M TECHNIQUE). Emulsification was performed at room temperature and cooling water was used as necessary. Each component in the following compositions was subjected to a sterilization treatment by a suitable sterilization method. Each operation of stirring/emulsifying etc. was performed under a sterile environment."

"<Example 1: preparation of vaccine 1>"

"In accordance with the composition of W/0-1 in Table 1, each component other than the antigen suspension was weighed and placed in a beaker. A polyoxyethylene hydrogenated castor oil was heated to 50°C and dissolved before use. An aqueous solution of at a weight ratio of 1/1, stirred and added. The remaining sorbitan sesquioleate was added as it was. Thereto was added gradually the antigen suspension with stirring and mixed by stirring at 12,000 rpm for 5 min at normal temperature in CLEARMIX CLM-0.8S (M TECHNIQUE) to give a W/0 type emulsion (W/0-1)."

"According to the composition of the outer aqueous phase 1 in Table 3, each component was dissolved in phosphate buffered saline (PBS, pH 7.4) (outer aqueous phase 1). The above-mentioned in a beaker and mixed using CLEARMIX CLM-0.8S at 9,000 rpm for 5 min to give an oil adjuvant vaccine 1. In the following Examples and Comparative Examples, the W/0 emulsion and the outer aqueous phase were mixed under the same conditions as in Example 1 for vaccine preparation, unless particularly specified."

It is the Examiner's position that, whereas the method disclosed in Applicant's argument is straightforward and easy to follow, the method, as set forth in the specification is not. For example, it is unclear just what "CLEARMIX CLM-0.8S (M TECHNIQUE)" consists of. Additionally, lines 5-6 of the example disclose that "The remaining sorbitan sesquioleate was added as it was." It is unclear what this sentence means. These are examples of numerous instances throughout the specification wherein it is impossible to ascertain the precise steps and components involved in making the vaccine of the instant claims. Accordingly, it is the Examiner's position that the specification fails to teach how to make the vaccine of the instant claims.

Further note the breadth of the claimed vaccine. At page 7 it is disclosed "The antigen solution used here may have any form as long as it is a liquid, and is exemplified by solution, suspension and the like." Clearly, the specification indicates that the antigen need not even be aqueous. Accordingly, the single disclosure regarding the efficacy of a single antigen cannot be considered adequate to support (and thus disclose how to use) all of the potential vaccines encompassed by the instant claims.

Applicant continues with a discussion of the apparent results of a single comparison of the vaccine of the instant claims to a vaccine absent the outer aqueous phase.

Again, a discussion of the properties and advantages of a single embodiment of the vaccine of the instant claims cannot adequately discloses how to make the vaccines encompassed by the instant claims and whether or not the specification adequately discloses how to use all the encompassed embodiments of said vaccine.

It remains the Examiner's position that the specification comprises a jumbled array of confusing Examples, Comparative Examples, and Experimental Examples, as well as numerous

confusing Tables, the combination of which do not adequately disclose how to make and use the vaccines encompassed by the instant claims.

4. Claims 1-15, and newly added claims 16-17, stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in Paper No. 12, mailed 11/01/02.

Applicant's arguments, filed 2/27/03, have been fully considered but they are not persuasive. Applicant does not argue the rejection independently, but argues that the specification provides a sufficient written description such that one of ordinary skill in the art could make and use the vaccines embodied by the pending claims. See the Examiner's response in Section 3, above.

5. The following are new grounds of rejection necessitated by Applicant's amendment.

6. Claims 5-17 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) The phrase, "wherein the inner aqueous phase is discontinuous and suspended in the oil component phase, and the oil component phase is discontinuous and suspended in the outer aqueous phase" in Claim 1, comprises a limitation not supported by the specification or claims as filed.

Applicant states that support for the new limitation can be found at page 4, line 37 through page 5, line 6, and at page 8, lines 16-21. However, the specific new limitation has not been found at these cites.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
April 28, 2003